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10/541,019	06/28/2005	Akira Tsuji	Q88424	4031

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EXAMINER	
PALENIK, JEFFREY T	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
02/03/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/541,019	TSUJI ET AL.	
	Examiner	Art Unit	
	Jeffrey T. Palenik	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 October 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,14,17 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,14,17 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6 Aug. 2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

STATUS OF THE APPLICATION

Receipt is acknowledged of Applicants' Request for Continued Examination (RCE), filed 13 October 2010. Said RCE enters the Amendments and Remarks filed 14 September 2010, in the matter of Application N° 10/541,019. The Examiner further acknowledges the following:

Claim 2-4 and 6-9 are newly cancelled.

Claims 1 and 5 have been amended with support. Claim 1 has been amended to more clearly indicate "peptide transporter 1" or PEPT1. Claim 5 is amended to properly depend from claim 1 only as claim 4 is now cancelled.

No claims have been added.

No new matter has been added.

Thus, claims 1, 5, 14, 17 and 22 now represent all claims currently under consideration.

INFORMATION DISCLOSURE STATEMENT

One new Information Disclosure Statement (IDS) filed 6 August 2010 is acknowledged and has been reviewed.

The Examiner notes that references submitted (e.g., USPN 5,753,253) provide suitable enablement in the art concerning the use of blends of Eudragit addressed in the Advisory Action mailed 27 September 2010.

MAINTAINED REJECTIONS

The following rejections are maintained from the previous Office Correspondence dated 15 April 2010 since the art which was previously cited continues to read on the amended/newly cited limitations.

CLAIM REJECTIONS - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5, 14, 17 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Timmins et al. (USPN 6,660,300) [emphasis added to reflect cancelled claims].

The instantly amended claims 1 and 17 are drawn to a gastrointestinally-absorbed, pharmaceutical preparation comprising a mixture of the following components: 1) a compound recognized by a proton-coupled transporter, and 2) a pH-sensitive polymer. Claim

22 further limits the compositions of either claim 1 or 17 such that it narrows the amount of the pH-sensitive polymer to 10-20% based on the weight of the entire preparation.

The invention of Timmins is directed to biphasic-controlled release systems having both an inner solid particulate phase and an outer solid continuous phase. Said phases range in ratio from to one another from 0.5:1 (e.g. 1:2) to 4:1 (col. 9, lines 54-58). Both the inner and outer phases are expressly taught as comprising hydrophobic polymers preferably ranging from 35-60% by weight of the entire composition (col. 10, lines 24-34). Hydrophilic polymers which are expressly taught as being incorporated into the formulations include both methacrylic acid copolymers "L" and "S" or Eudragit L and Eudragit S (col. 10, lines 44-51). Regarding the limitations of claim 22 wherein said range is narrowed to 10-20 wt% of the entire composition, the invention of Timmins also expressly teaches that the inner phase may comprise from about 15 to about 95% by weight in the form of hydrophobic polymers (col. 9, lines 59-67).

Those types of or particular compounds which act on the PEPT1 transporter of claim 1, are recited in claim 5.

Regarding the forgoing limitations for the compounds which act upon particular transporters, Timmins expressly teaches that numerous compounds may be delivered by the biphasic composition. Many different types of peptides are taught, including those which comprise amino acids such as proline and glycine (col. 17, line 28 to col. 18, line 47). Other non-peptide forms of active agents are taught such as captopril, a known acetylcholinesterase inhibitor (col. 18, lines 53-55). The forgoing agents which are taught represent examples of those compounds which are recited in both claims 5 and 9. Compounds which are expressly

taught by Timmins and which are recited include those such as salicylic acid (e.g. aspirin and p-aminosalicylic acid) and nicotinic acid (col. 15, lines 6 and 19-20).

Claim 14 recites that the composition of claim 1 is an oral dosage form. Oral dosage forms are taught throughout the entire invention to Timmins (see for example the Abstract).

Thus, it would have been prima facie obvious to a person of ordinary skill at the time the invention was made to have prepared the mixed composition as instantly claimed under the guidance of the practiced invention of Timmins et al. The ordinarily skilled artisan would have been highly motivated to do so and would have had an equally high expectation of successfully arriving at the instantly claimed release composition, particularly since Timmins expressly teaches or suggests each of the above limitations. Of particular note, is that Timmins teaches that the active compound, which is released to the target transporters, is mixed into the formulation with particles of hydrophobic polymers, rather than being coated by a film of said polymers. Since this key distinction in Applicants' invention is met by the art, it is the conclusion of the Examiner that Applicants' invention as a whole would have been prima facie obvious at the time the invention was made, especially in the absence of evidence to the contrary.

RESPONSE TO ARGUMENTS

Applicants' arguments with regard to the rejection of claims 1, 5, 14, 17 and 22 under 35 USC 103(a) as being unpatentable over the teachings of Timmins et al. have been fully considered but they are not persuasive.

The crux of Applicants' assertions is that Timmins not only fails to "specifically disclose a pharmaceutical preparation comprising a peptide transporter 1", but also the use of a pH-sensitive polymer present between 5-40 wt% of the entire pharmaceutical preparation.

Concerning the polymers which are expressly taught by the reference, Applicants' fully acknowledge that polymers such as Eudragit "L", "S" and "L100-55" are taught. Applicants' then further assert that the reference does not disclose, teach or suggest that the pH-sensitive polymer is present in an amount of 5-40 wt% of the entire composition and that Timmins does not recognize the importance of the pH-sensitive polymer.

The Examiner respectfully disagrees with both of these points. Timmins, as well as the ordinarily skilled artisan, clearly recognize the importance of the pH-sensitive polymer. At the very least, Timmins' use of the tradenames and blend designations for the different Eudragit compounds demonstrates an understanding that not all Eudragit blends function the same. Even were that assumption to be made, it would be well within the purview of the ordinarily skilled artisan to research and ascertain the differences and capabilities of each blend, again as evidenced by Applicants' attachments to the response. Concerning the amount of polymer admixed with the recognized compound, Timmins clearly discloses that the amount of polymer which may be used, ranges as broadly as from 5-95 wt% and preferably from 7-85 wt% of the composition (col. 9, lines 59-67 and col. 10, lines 9-16). At the very least, the instantly claimed range is both taught and suggested by the preferred range. Applicants have provided no showing of evidence to suggest otherwise.

Lastly, Applicants' discussion of Example 2 and Figure 2 (Remarks, pg. 10) pitting the "L 100-55" blend against the "RS" blend of Eudragit is unpersuasive. At the very least, the

"RS" blend is not excluded from the instantly claimed composition as said composition is recited as "comprising" components (a) and (b). See MPEP §2111.03. Furthermore, the composition, as instantly claimed, is not commensurate in scope with the cited Examples of the specification (e.g., Examples 2 and 4).

For these reasons, Applicants' arguments are found unpersuasive. Said rejection is therefore **maintained**.

NEW REJECTIONS

In light of Applicants' amendment of the base claim and newly submitted art (see new IDS), the following rejection(s) are presented:

CLAIM REJECTIONS - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 14, 17 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Suzuki et al. (JP H09-188617; IDS Reference; Machine Translation provided).

The instant invention is a composition comprising a mixture of a compound recognized by peptide transporter 1 or "PEPT1" and 5-40 wt% of a pH-sensitive polymer.

Suzuki provides clear anticipation of the instant invention in claims 1 and 2 and ¶¶[0018]-[0019]. Claims 1 is drawn to a sustained-release composition containing (e.g.,

comprising) an enteric polymer and a medicine. Claim 2 and §[0018] respectively teach the copolymer and tradename (e.g., Eudragit or Oidoragitto) blends instantly claimed. Paragraph [0018] further teaches that the enteric polymer may be embodied by the instantly claimed HPMC acetate succinate or phthalate. Claim 3 and §[0019] disclose that said enteric polymer will most preferably range from 5-15.3 wt% of the dosage form. Lastly, §[0022], in addition to teaching that the dosage form is used internally (e.g., orally dosed), it is taught that the drugs which may be incorporated into the formulation include anti-tumor agents, chemotherapeutic agents and such β-lactam antibiotics as methicillin. As such the reference is considered as teaching each of the instantly claimed limitations.

All claims have been rejected; no claims are allowed.

CORRESPONDENCE

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information

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/Jeffrey T. Palenik/
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner
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